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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

K963709

Device: Cement-On Femoral Stem

Classification Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis (CFR 888.3560)

Intended Use: When used with the AGC and Maxim Knee systems, the indications for use of the Cement-On Femoral Stem include: 1) painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved, 2) failure of a previous joint replacement procedure, 3) correction of varus, valgus, or post traumatic deformity and 4) correction of revision of unsuccessful osteotomy or arthrodesis.

This device is for use with bone cement.

Device Description: The Cement-On Femoral Stem enhances fixation of prosthesis to bone while still being able to maintain the posterior cruciate ligament. The stem is indicated when the soft tissues of the knee are intact but significant bony loss or fracture warrants the use of an intramedullary stem.

The Cement-On Femoral Stem is a Co-Cr 6mm distal augment with an attached 120mm long intramedullary stem. The stem is angled at 7° valgus and is fixed to the surface of the primary femoral component with bone cement.

The device is to be used with the appropriate AGC and Maxim knee components and is available in six different sizes.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to the bone cement
Deformity of the joint
Cardiovascular disorders
Fracture of the cement
Implant loosening/migration
Nerve damage

Blood vessel damage
Soft tissue imbalance
Delayed wound healing
Metal sensitivity
Fracture of the component

Bone Fracture
Infection
Hematoma
Dislocation
Excessive wear

Substantial Equivalence: In function and overall design, the Cement-On Femoral Stem is equivalent to other knee components on the market. These stems include:

AGC 2000 Total Knee Prothesis (Biomet, Inc., Warsaw, IN)

Maxim Knee System (Biomet, Inc., Warsaw, IN)

Kinemax Plus Total Knee System (Howmedica, Rutherford, New Jersey)

Genesis Total Knee System (Richards, Memphis, TN)